



Robert Greene Sterne  
Jorge A. Goldstein  
David K.S. Cornwell  
Robert W. Esmond  
Tracy-Gene G. Durkin  
Michele A. Cimbalà  
Michael B. Ray  
Robert E. Sokohl  
Eric K. Steffe  
Michael Q. Lee  
Steven R. Ludwig  
John M. Covert  
Linda E. Homer  
Robert C. Millonig  
Donald J. Featherstone  
Timothy J. Shea, Jr  
Michael V. Messinger  
Judith U. Kim

Patrick E. Garrett  
Jeffrey T. Helvey  
Heidi L. Kraus  
Eldora L. Ellison  
Thomas C. Fiala  
Donald R. Banowitz  
Peter A. Jackman  
Jeffrey S. Weaver  
Brian J. Del Buono  
Vincent L. Capuano  
Virgil Lee Beaton  
Theodore A. Wood  
Elizabeth J. Haanes  
Joseph S. Ostroff  
Frank R. Cottingham  
Rae Lynn P. Guest  
Daniel A. Klein  
Jason D. Eisenberg

Michael D. Specht  
Tracy L. Muller  
Jon E. Wright  
LuAnne M. DeSantis  
Ann E. Summerfield  
Helene C. Carlson  
Cynthia M. Bouchez  
Timothy A. Doyle  
Gaby L. Longworth  
Lori A. Gordon  
Ted J. Ebersole  
Laura A. Vogel  
Bryan S. Wade  
Bashir M.S. Ali  
Shannon A. Carroll  
Matthew E. Kelley  
Michelle K. Holoubek  
Marsha A. Rose\*

W. Blake Coblenz\*  
James J. Pohl\*  
John T. Haran\*  
Mark W. Rygiel

**Registered Patent Agents\***  
Karen R. Markowicz  
Matthew J. Dowd  
Katrina Yujuan Pei Quach  
Bryan L. Skelton  
Robert A. Schwartzman  
Teresa A. Colella  
Victoria S. Rutherford  
Simon J. Elliott  
Julie A. Heider  
Mita Mukherjee  
Scott M. Woodhouse  
Christopher J. Walsh

Liliana Di Nola-Burns  
Peter A. Socarras  
Jeffrey Mills  
Danielle L. Letting  
Lori Brandes

**Of Counsel**  
Edward J. Kessler  
Kenneth C. Bass III  
Marvin C. Guthrie

\*Admitted only in Maryland  
\*Admitted only in Virginia  
\*Practice Limited to  
Federal Agencies

February 21, 2006

**WRITER'S DIRECT NUMBER:**  
(202) 772-8606  
**INTERNET ADDRESS:**  
ANNS@SKGF.COM

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Mail Stop: Amendment**

Re: U.S. Utility Patent Application  
Application No. 10/698,928; Filed: October 31, 2003  
For: **Novel Cytarabine Monophosphate Prodrugs**  
Inventors: Boyer *et al.*  
Our Ref: 2358.0180002/RWE/AES

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Credit Card Payment Form (PTO-2038) in the amount of **\$180.00** to cover Information Disclosure Statement Filing fee (37 C.F.R. § 1.17(p));
2. Second Supplemental Information Disclosure Statement Under 37 C.F.R. § 1.97(c);
3. Two (2) pages of Form PTO/SB/08B citing eleven (11) documents (Documents II-JS);
4. Copies of the eleven (11) cited documents; and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
February 21, 2006  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in cursive script, reading "Ann E. Summerfield".

Ann E. Summerfield  
Attorney for Applicants  
Registration No. 47,982

RWE/AES:law  
Enclosures

499211\_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

BOYER *et al.*

Appl. No.: 10/698,928

Filed: October 31, 2003

For: **Novel Cytarabine Monophosphate  
Prodrugs**

Confirmation No.: 2990

Art Unit: 1626

Examiner: T. Solola

Atty. Docket: 2358.0180002/RWE/AES

**Second Supplemental Information Disclosure Statement  
Filing Under 37 C.F.R. § 1.97(c)**

***Mail Stop Amendment***

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Second Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' First Supplemental Information Disclosure Statement filed on January 18, 2006 in connection with the captioned application. Copies of all documents cited on accompanying Form PTO/SB/08B, documents **JI-JS**, are submitted herewith.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier or later than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS

Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Second Supplemental Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return copies of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Ann E. Summerfield  
Attorney for Applicants  
Registration No. 47,982

Date: February 21, 2006

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

499163\_1.DOC



PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Project (07-05), no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				Application Number	10/698,928
				Filing Date	October 31, 2003
				First Named Inventor	Serge Boyer
				Art Unit	1626
				Examiner Name	Solola, Taofiq A.
Sheet	1	of	2	Attorney Docket Number	2358.0180002/RWE/AES

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	J1	BRAESS, J. <i>et al.</i> "Oral Cytarabine Octosfate in Acute Myeloid Leukemia and non-Hodgkin's Lymphoma - Phase I/II Studies and Pharmacokinetics", <i>Leukemia</i> 12:1618-1626, Stockton Press (1998)	
	JJ	CHABNER, B.A., "Cytidine Analogues", in <i>Cancer Chemotherapy: Principles and Practice</i> , Lippincott Williams & Wilkins (April 1990)	
	JK	CHABNER, B.A., <i>et al.</i> , "Purification and Properties of Cytidine Deaminase from Normal and Leukemic Granulocytes", <i>Journal of Clinical Investigation</i> 53:922-931, American Society for Clinical Investigation (March 1974)	
	JL	COHEN, S.S. "The Mechanisms of Lethal Action of Arabinosyl Cytosine (araC) and Arabinosyl Adenine (araA)", <i>Cancer</i> 40:509-518, Wiley (1977)	
	JM	GRANT, S., "Biochemical Modulation of Cytosine Arabinoside", <i>Pharmac. Ther.</i> 48:29-44, Pergamon Press plc (1990)	
	JN	LEACH, W.B. <i>et al.</i> "Toxicity Studies in Mice Treated with 1-β-D-Arabinofuranosyl-cytosine (ara-C)", <i>Cancer Research</i> 29:529-535, American Association for Cancer Research (March 1969)	
	JO	PLUNKETT, W. <i>et al.</i> "Pharmacologically Directed Ara-C Therapy for Refractory Leukemia", <i>Seminars in Oncology</i> 12(2) Suppl. 3:20-30, W.B. Saunders (June 1985)	
	JP	RUSTUM, Y.M., <i>et al.</i> "1-β-Arabinofuranosylcytosine in Therapy of Leukemia: Preclinical and Clinical Overview" <i>Pharmac. Ther.</i> 56:307-321, Pergamon Press Ltd. (1992)	
	JQ	SHIMMA, N. <i>et al.</i> , "The Design and Synthesis of a New Tumor-Selective Fluoropyrimidine Carbamate, <i>Capecitabine</i> " <i>Bioorganic &amp; Medicinal Chemistry</i> 8:1697-1706, Elsevier Science Ltd. (2000)	
	JR	SUTO, T. <i>et al.</i> "The Effect of YNK-01 (an Oral Prodrug of Cytarabine) on Hepatocellular Carcinoma" <i>Seminars in Oncology</i> 24(2) Suppl 6:S6-122-S6-129, W.B. Saunders (April 1997)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

